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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Application No. Applicant(s) 10/743.621 KNUDSEN ET AL. Office Action Summary Examiner Art Unit ANITA C. MOLINA 4194 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 22 December 2003. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-46 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-46 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date.

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SE/08) Paper No(s)/Mail Date _

Notice of Informal Patent Application

6) Other:

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DETAILED ACTION

Oath/Declaration

The oath or declaration is missing. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Claim Rejections - 35 USC § 101

1 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 33-36 are directed to non-statutory subject matter.

An electronic database does not fall within any of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter) because it is functional descriptive material which does not define any structural and functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized.

An electronic database is directed to non-functional descriptive material and it is not directed to a practical application of such because the claim does not require any physical transformation and the invention as claimed does not produce a useful, concrete, and tangible result.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claim 1 recites the limitations "said syndrome" in line 3, and "said symptoms" in
 line 6. Claim 10 recites the limitation "said predetermined rules" in line 1. Claim 17
 recites the limitation "the user" in line 22 of page 7. There is insufficient antecedent
 basis for these limitations in these claims.
- 3. Claims 1, 2, 4, 11, 37, 40, 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of "and/or" is unacceptable as it makes indefinite the scope of the claim. Please replace with either "and" or "or". For the purposes of this examination, the claims will be treated as reading "or".
- 4. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "near automatic" in claim 35 is a relative term which renders the claim indefinite. The term "near automatic" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The examiner will interpret this claim to read "allow automatic extraction".

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Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 1-4, 6-10, and 40-46 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6.277.071 to Hennessy et al. hereinafter. Hennessy.

As per claim 1, Hennessy teaches a method for interactive home treatment of a patient suffering from a disease, said method comprising the steps of:

- -a. collecting information from said patient regarding one or more episodes related to said syndrome (see: column 5, lines 50-56), and
- -b. analyzing said information, wherein said analyzing comprises identifying the presence or absence of predetermined patterns of said symptoms; actions, indicators, or changes (see: column 5, lines 59-62).

As per claim 2, Hennessy teaches the claimed method, wherein the disease comprises a chronic and/or episodic syndrome (see: column 6, lines 3-11) and said collected information comprises one or more of:

- -(i) the nature, severity, or timing of symptoms, wherein said symptoms may comprise one or more clinical indicators (see: column 6, lines 30-40);
- -(ii) one or more predisposing factors that are predictive of onset of an episode (see: column 6, 26-29);

 -(iii) one or more actions related to treatment that have been self-administered by the patient or administered to the patient by a surrogate (see: column 6, lines 42-45);
 and

-(iv) one or more changes in the symptoms, indicators, factors, or actions over time (see: column 6, lines 45-48).

As per claim 3, Hennessy teaches the claimed method, further comprising providing feedback to said patient based on said analysis (see: column 5, lines 60-67).

As per claim 4, Hennessy teaches the claimed method, wherein

- -(i) said collecting **or** providing step is achieved using a microprocessor (see: column 5, line 54) having storage means capable of storing said information (see: column 5, lines 35-38), an input means (see: column 5, lines 43-48), a display operationally connected to the microprocessor (see: column 12, lines 34-37), and a means for transmitting said information to a second device (see: local area network, column 5, lines 43-48); and
- -(ii) said analyzing step is achieved using a central computer capable of receiving and analyzing said transmitted information and providing said feedback (see: column 5, lines 59-67).

As per claim 6, Hennessy teaches the claimed method, wherein said analyzing comprises application of one or more rules to said information (see: column 5, lines 59-67).

As per claim 7, Hennessy teaches the claimed method wherein said rules comprise one or more of:

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 -(i) a specified threshold time interval during which the patient has not reported any data;

- -(ii) a specific threshold time interval from onset of a particular symptom to administration of treatment:
- -(iii) a specified threshold number of self-treatment actions to treat one particular episode; and
 - -(iv) a specified clinical outcome of the episode.

Hennessy teaches using American Diabetes Association recommended guidelines as alarm thresholds for rules. It is inherent that the parameters of the rules taught by Hennessy would include the guidelines of the ADA (see: column 8, lines 24-41). The ADA teaches the claimed rules (see at least: ADA, page 30, 4th paragraph).

As per claim 8, Hennessy teaches the claimed method, wherein said disease is selected from the group consisting of diabetes, hemophilia, asthma, chronic liver disease, hypertension, acquired immune deficiency syndrome, multiple sclerosis, rheumatoid arthritis, and other autoimmune diseases, epilepsy, chronic or recurring viral infections, chronic kidney insufficiency with home dialysis, chronic myocardial insufficiency, chronic anticoagulant treatment, Crohn's disease, ulcerative colitis, sickle cell anemia, thallasemia, malaria, cancer, chronic pain syndrome, peripheral vascular disease, and chronic substance abuse (see: column 6, lines 6-11).

As per claim 9, it is rejected for the same reasons set forth for claim 3.

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As per claim 10, Hennessy teaches the claimed method, wherein said predetermined rules are modified for a single patient based on said repeated information and analysis (see: column 9, lines 50-59).

As per claim 40, Hennessy teaches a system for monitoring the treatment of a patient over a communication network, the system comprising:

- -a means for allowing the patient to input data about self treatment steps taken by the patient and/or symptoms observed by the patient (see: column 6, lines 30-45);
- -a means for allowing a clinic to input data about clinical treatment of the patient (see: column 5, lines 50-53);
- a means for processing the patient inputted data and the clinic inputted data and for storing the data in a database (see: column 5, lines 30-53); and
- -a means for allowing a medical practitioner to access the data in the database (see: column 5, lines 30-53).

As per claim 41, Hennessy teaches the claimed system, further comprising a means for allowing the medical practitioner to manipulate the data in the database (see: column 10, lines 28-56).

As per claim 42, Hennessy teaches the claimed system, wherein the means for allowing the medical practitioner to manipulate the data utilizes a set of predetermined rules (see: column 10, lines 28-56).

As per claim 43, Hennessy teaches a system for monitoring the treatment of a patient over a communication network, the system comprising:

-a means for allowing the patient to input data about self treatment steps taken by the patient **or** symptoms observed by the patient (see: column 6, lines 30-45);

- -a means for allowing a clinic to input data about clinical treatment of the patient (see: column 5. lines 50-53);
- -a database for storing the clinic-inputted data and the patient-inputted data (see: column 5, lines 30-53);
- -a means for applying a set of rules to the data to manipulate the data (see: column 10, lines 28-56); and
- -a means for allowing a medical practitioner to access the data in the database (see: column 5, lines 30-53);
- -wherein the database (i) is stored at a location other than the clinic or (ii) is not under control of the patient (see: column 6, lines 1-2).

As per claim 44, Hennessy teaches a method for assisting in the treatment of a patient having a medically prescribed treatment regimen, the method comprising the steps of:

- -a. collecting directly from the patient data relating to patient-observed symptoms or patient-directed self-treatment steps (see: column 6, lines 30-45);
- -b. collecting from a clinic data relating to (i) a patient's symptoms observed by practitioners in the clinic or (ii) a treatment administered by the clinic (see: column 5, lines 50-53);
- -c. storing the data collected in steps (a) and (b) at a central location (see: column 6, lines 1-2); and

 -d. providing access to the data in step c to a medical practitioner (see: column 5, lines 30-53).

As per claim 45, Hennessy teaches the claimed method, further comprising the step of providing the medical practitioner with a means to analyze the data to adjust the patient's treatment regimen (see: column 8, lines 24-63).

As per claim 46, Hennessy teaches the claimed method, wherein the medical practitioner is provided with tools to economically optimize the patient's treatment regime without adversely affecting the patient's health (see: column 8, lines 24-63).

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US
 6,277,071 to Hennessy et al in view of US 2002/0019749 to Becker et al, hereinafter,
 Becker.

As per claim 5, Hennessy does not teach the claimed method, wherein said collecting comprises entry by said patient of said information using a handheld computer. Hennessy does teach entry of information using a computer (see: column 5, lines 43-48). Becker teaches using a handheld computer to enter patient information (see: paragraph 80). It would have been obvious to one of ordinary skill in the art to

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include in the information entry devices of Hennessy, the handheld computer as taught by Becker because the claimed invention is merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

 Claim 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,277,071 to Hennessy et al in view of US 2002/0032384 to Raymond et al, hereinafter, Raymond.

As per claim 11, Hennessy teaches a method for assisting in the treatment of a disease, the method comprising the steps of:

- -(i) collecting from a plurality of patients information relating to symptoms or selftreatment of the disease via a handheld electronic device (see: column 5, lines 52-56);
- -(ii) transmitting the information collected by the handheld device to a database (see: column 5, line 32);
 - -(iii) analyzing the data in the database (see: column 5, line 59-62);
- -(iv) providing the results of the analysis to a health care professional treating one of the plurality of patients (see: column 5, lines 60-67).

Hennessy fails to teach the claimed method steps comprising:

 -(v) receiving from the health care professional a message for the one patient (see: cou; and

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-(vi) transmitting the message to the one patient's handheld electronic device. However, Raymond teaches sending a message to the patient (see: paragraph 160) and the patient using a handheld device (see: paragraph 145). It would have been obvious to one of ordinary skill in the art to include in the messaging of Hennessy, the message to a patient and the handheld device as taught by Raymond because the claimed invention is merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

As per claim 12, Hennessy teaches the claimed method, wherein the analysis step comprises applying a predetermined set of rules to the data (see: column 5, lines 59-67).

As per claim 13, Hennessy teaches the claimed method, wherein the predetermined rules comprise general rules, group rules, and individual rules (see: column 5, lines 38-48).

As per claim 14, it is rejected for the same reasons set forth for claim 11.

As per claim 15, it is rejected for the same reasons set forth for claim 12.

As per claim 16, Hennessy teaches the claimed method, wherein the rules may be modified by the health care professional, the patient, or both (see: column 8, lines 41-45).

 Claims 17-19, 21-22, 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,277,071 to Hennessy et al in view of US 2002/0033753 to Imbo.

As per claim 17, Hennessy teaches the system comprising a patient interface device comprised of:

- -(i) a memory unit (see: column 5, lines 35-38);
- -(ii) a display unit (see: column 5, lines 45-48);
- -(iii) an input means (see: column 5, lines 43-48);
- -(iv) a communication means for communicating over a network (see: column 5, line 47):
- -(v) a processor interfaced with the memory unit, the display unit, the input means, and the communication means (see: column 5, lines 54-56), wherein the processor:
- --upon entering an activation mode, is configured to prompt the user to enter data related to the patient's treatment of the disease (see: column 9, lines 29-33);
- --is configured to store the data in the memory prior to exiting the activation mode (see: column 9, line 43); and
 - -an analysis tool having a second processor configured:
- --to receive, from the network, the patient data relating to the patient's treatment of the disease and the follow-up data (see: column 5, lines 57-67);
- --to apply a predetermined set of disease specific rules to generate an analysis of the data and follow-up data (see: column 5, lines 59-67):

- --to generate a message based on the analysis (see: column 5, lines 59-67);
- --to generate, upon request, a report based on the analysis (see: column 6, lines 45-51); and
 - --to transmit the message over the network (see: column 5, lines 59-67).

Hennessy does not teach, upon re-entering the activation mode, is configured to prompt the user to enter follow-up data relating to previously reported data; and is configured to transmit the data and follow-up data over the network to one or more network addresses. Imbo teaches prompting a user to enter follow-up data and transmitting that data over a network (see: paragraph 178). It would have been obvious to one of ordinary skill in the art to include in the analysis tool of Hennessy, the prompting for entry of follow-up data as taught by Imbo because the claimed invention is merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

As per claim 18, Hennessy teaches the claimed system, wherein the message is transmitted to a treating health care professional (see: column 5, lines 59-67).

As per claim 19, Imbo teaches the claimed system, wherein the message is transmitted to the patient interface device.

As per claim 21, Hennessy teaches the claimed system, wherein the input means for the patient interface device comprises a barcode reader and a touch screen (see: Figure 1 and column 5, line 30 – column 6, line 2).

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As per claim 22, Hennessy teaches the claimed system, wherein the database contains data and follow-up data from a plurality of patients having the same disease (see: column 5, lines 30-59 and column 6, lines 30-51).

As per claim 26, Hennessy teaches the claimed system, wherein the patient interface device further comprises a medical monitor for monitoring one or more specific parameters related to the patient's disease (see; column 5, lines 57-59).

As per claim 27, Hennessy teaches the claimed system, wherein the medical monitor monitors a bodily parameter (see: column 6, lines 30-42).

As per claim 28, Hennessy teaches the claimed system, wherein the parameter is a blood parameter (see: column 6, lines 30-42).

As per claim 29, Hennessy teaches the claimed system, wherein the blood parameter comprises at least one of blood pressure, blood coagulation, haemoglobin, or creatinine (see: column 6, lines 30-42).

As per claim 30, it is rejected for the same reasons set forth for claim 17.

 Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,277,071 to Hennessy et al in view of US 2002/0033753 to Imbo and in view of US 2001/0056358 to Dulong et al, hereinafter, Dulong.

As per claim 20, Hennessy and Imbo fail to teach the claimed system, wherein the input means for the patient interface device comprises a barcode reader and a touch screen. Dulong teaches input devices such as a touch pad and a bar code scanner (see: paragraph 26).

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 Claims 23-25, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,277,071 to Hennessy et al in view of US 2002/0033753 to Imbo and in view of US 2003/0055685 to Cobb et al. hereinafter. Cobb.

As per claim 23, Hennessy and Imbo do not teach the claimed system, wherein the patient interface device further comprises drug delivery device. Cobb teaches a drug delivery device attached to a monitoring system (see: paragraph 30). It would have been obvious to one of ordinary skill in the art to include in the patient interface device of Hennessy and Imbo, the drug delivery device as taught by Cobb because the claimed invention is merely a combination of old elements, and in the combination, each element merely would have performed the same function as is did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

As per claim 24, Hennessy teaches the claimed system, wherein the drug delivery device is configured to deliver a therapeutic agent for the treatment of hemophilia (see: column 6. lines 6-11).

As per claim 25, Hennessy teaches the claimed system, wherein the drug delivery device is configured to deliver a therapeutic agent for the treatment of diabetes (see: column 6, lines 6-11).

As per claim 36, Imbo teaches the claimed database (taught by Cobb and Hennessy), wherein the data comprises follow-up data collected after the administration

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of the self-treatment in response to the onset of the symptom and wherein the follow-up data is related to the resolution of the symptom (see: paragraph 178).

 Claims 31-35, and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0055685 to Cobb et al, hereinafter, Cobb in view of US 6.277.071 to Hennessy et al, hereinafter, Hennessy.

As per claim 31, Cobb teaches a system for analyzing patient data from one or more patients with a disease, the system comprising:

- -(i) a communication means for receiving data collected contemporaneously with an administration of a self-treatment or an onset of a symptom of the disease (see: paragraph 63);
- -(ii) a processor configured to apply a predetermined set of criteria to the data to generate an analysis of the data (see: paragraph 52).

Cobb fails to teach the processor configured to generate a patient message based on the analysis; and (iii) a means for transmitting the message based on the analysis over the network to the patient. Hennessy teaches these limitations in column 5, lines 60-67). It would have been obvious to one of ordinary skill in the art to include in the system for analyzing patient data of Cobb, the messages about the analysis as taught by Hennessy because the claimed invention is merely a combination of old elements, and in the combination, each element merely would have performed the same function as is did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

As per claim 32, Cobb teaches the claimed system, further comprising a patient data input means for collecting the contemporaneous data associated with the self-administration of the treatment or the onset of the symptom of the disease. (see: paragraph 61).

As per claim 33, Cobb teaches an electronic database for assisting in the selftreatment of a disease, the database comprised of:

(ii) data from a plurality of patients who have the same disease, the data relating to one or more symptoms of the disease and self-administered treatments for the disease that are administered for prevention of symptoms or in response to the symptom(s), the data being collected contemporaneously with the onset of the symptom(s) or the administration of the treatments (see: paragraph 63). Cobb fails to teach (i) a data element representative of the disease being treated. Hennessy teaches the type of diabetes as a data element in a database (see: column 6, lines 18-29). The reasons for combining these references are the same as set forth for claim 31.

As per claim 34, Cobb teaches the claimed database, wherein the database is accessible over a network by a patient input device having a first network address and an analysis tool having a second and distinct network address (see: paragraph 54).

As per claim 35, Hennessy teaches the claimed database, wherein the database is organized by an analytic tool to allow near automatic extraction of medically useful information relating to treatment of the disease by a health care professional (see: column 10, line 29 - column 11, line 8).

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As per claim 37, Cobb teaches a method for assisting in the treatment of a patient with a disease comprising the steps of:

- -(i) recording data related to self-administration of a treatment for the disease or a symptom of the disease contemporaneously with onset of the symptom or the administration of the self-treatment (see: paragraph 63);
- -(ii) transmitting the data over a network to a database that is accessibly by an analysis tool (see: paragraph 54);
- -(iii) analyzing the data with the analysis tool by applying a predetermined set of rules to the data (see: paragraph 52). Cobb fails to teach (iv) generating a physician or care-giver report and/or a patient message based on the analysis; and (v) transmitting the message to the patient over the network. Hennessy teaches the limitations in column 5, lines 59-67, where a message is generated and send to the patient over the network (e.g. through an e-mail). The reasons for combining these references are the same as set forth for claim 31.

As per claim 38, it is rejected for the same reasons set forth for claim 34.

As per claim 39, Hennessy teaches the claimed method, wherein the message is transmitted to a health care professional (see: column 5, lines 59-67).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANITA MOLINA whose telephone number is (571)270-3614. The examiner can normally be reached on Monday through Friday 8am to 5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Kyle can be reached on 571-272-6746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anita C. Molina/ Examiner, Art Unit 4194 05/09/2008

> /Charles R. Kyle/ Supervisory Patent Examiner, Art Unit 4194